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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,147	01/29/2004	Andries Jan Smit	VOB-34537US1	4624

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EXAMINER	
BERHANU, ETSUB D	
ART UNIT	PAPER NUMBER
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/767,147	SMIT ET AL.	
	Examiner	Art Unit	
	ETSUB D. BERHANU	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-40,43-58 and 60-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-40,43-58 and 60-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/3/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 32, 33, 37-40, 43-45, 47, 48, 51-57, 60 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kollias et al.'059 (previously cited) further in view of Carim et al.'226 (USPN 5,755,226).

Kollias et al.'059 discloses an instrument and method for measuring glucose concentrations by using fluorescence (see ABSTRACT). Figure 2 of Kollias et al.'059 discloses a light source 14 and a detector 18. Kollias et al.'059 discloses: an illumination area of 0.2 cm^2 (col. 5, lines 57-58); use of wavelengths in the range of 300-345 nm (col. 5, lines 27-32); a measuring window of detector 18 is held away from the surface of the skin since contact with the skin is made using a probe comprising optical fibers (see Figure 10A and col. 6, lines 51-53); an excitation wavelength of 420nm and an emission wavelength of 500 nm (col. 6, lines 46-67); reflected radiation being detected (see Figures 10A and 10B); multiple wavelengths in a normalizing section for determining glucose (col. 10, line 59 – col. 11, line 12), wherein normalizing one wavelength by using another wavelength is considered to be aggregating detected fractions of fluorescent radiation to an aggregated amount of detected electromagnetic radiation; ends of optical fibers (Figures 10A and 10B), wherein the ends include an irradiation and measuring window, and wherein the ends move relative to a measuring window of the detector which is located in the analyzing instrument, when the fiber is placed on the skin, the fiber and windows capable of being placed at an angle of 25-65 degrees relative to the skin surface; filters, lamps and laser diodes as light

sources (col. 6, lines 25-28, col. 14, lines 1-10, col. 9, line 65 – col. 10, line 3); irradiation being changed when measuring a reflected and emission radiation (col. 13, line 66 – col. 14, line 47); an irradiation being performed in a pulse fashion (col. 9, line 6 – col. 10, line 12); different wavelengths being chosen using a wavelength selector (Figure 11, element 107 and col. 13, line 66 – col. 14, line 47); a support structure (col. 7, line 65 – col. 8, line 20) and control means (Figure 2, element 12) for controlling the excitation radiation of a light source, wherein the control means allows the apparatus to be capable of intermittently irradiating skin tissue and for separately detecting radiation from the skin tissue.

Kollias et al.'059 discloses all the elements of the current invention, as discussed above, except for the size of the skin surface from which the measured fluorescent radiation is received being at least $1cm^2$. Kollias et al.'059 discloses that the probe used is a fiber optic device that allows the collection of data from different skin areas (col. 6, lines 51-53), but fails to disclose the details of the size of the fiber optic device. Carim et al.'226 teaches a fiber optic device having a 1.0cm diameter that is capable of collecting data from different skin areas on a body (col. 15, lines 62-64). It would have been within the skill of the art to use the fiber optic device of Carim et al.'226 as the fiber optic device of Kollias et al.'059 since Kollias et al.'059 requires the use of a fiber optic device to collect data, but fails to disclose the details of the fiber optic device, and Carim et al.'226 discloses details of a fiber optic device capable of collecting data from different skin sites on a patient.

3. Claims 32, 34-37, 47, 49, 50, 56-58 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al.'127 (previously cited) further in view of Carim et al.'226.

Anderson et al.'127 discloses a method and apparatus for delivering ultraviolet radiation for the analysis of skin (see ABSTRACT), the method and apparatus comprising: effected skin covering an area of $1cm^2$ (col. 3, lines 11-12); use of illuminators (Figure 1, elements 14 and 34) which deliver ultraviolet radiation and a detector (Figure 1, element 22); detecting reflected and fluorescent radiation (col. 3, line 65 – col. 4, line 4 and col. 17, lines 17-23); an array of detectors (col. 12, lines 14-16); a reference

measurement made in the form of a spectrometer reflectance ratio (Figure 4, element 138); a lamp as a light source (col. 9, lines 34-38); a spectrometer (Figure 1, element 49); and separate detectors for detecting reflected excitation radiation and fluorescent radiation (col. 12, lines 22-32). Figure 2 discloses that a measuring window (the CCD camera) is held at an angle of 25-65 degrees relative to the irradiated surface of the skin.

Anderson et al.'127 discloses all the elements of the current invention, as discussed above, except for the size of the fiber optic bundle (col. 16, lines 33-43) used to carry the diagnostic radiation to the skin and to receive the resulting diagnostic signal radiation from the skin. Carim et al.'226 teaches a fiber optic bundle having a 1.0cm diameter that is capable of carrying diagnostic radiation to the skin of a patient and also capable of receiving the resulting diagnostic signal radiation from the skin (col. 15, lines 62-64). It would have been within the skill of the art to use the fiber optic bundle of Carim et al.'226 as the fiber optic bundle of Anderson et al.'127 since Anderson et al.'127 requires the use of a fiber optic bundle to deliver and receive diagnostic radiation signals from the skin of a patient, but fails to disclose the details of the fiber optic bundle, and Carim et al.'226 discloses details of a fiber optic bundle capable of delivering and receiving diagnostic radiation signals from the skin of a patient. Regarding claims 66, 49 and 50, Anderson et al.'127 teaches that fiber optic bundles comprising separate radiation and delivery fibers are an alternate equivalent to a fiber optic bundle comprising a single fiber wherein the single fiber both delivers and receives diagnostic radiation data to and from the skin of a patient (col. 17, lines 55-67). It would have been within the skill of the art to substitute a fiber optic bundle comprising a single optic fiber to both deliver radiation and receive radiation from the same skin site since it has generally been held within the skill of the art to substitute alternate equivalent expedients.

4. Claims 62-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kollias et al.'059 further in view of Anderson et al.'127.

Kollias et al.'059 discloses all the elements of the current invention, as discussed above, except for the measured fluorescent radiation being received from a portion of the irradiated surface portion of the skin only, wherein the size of the skin surface from which the measured fluorescent radiation is received is larger than $0.1cm^2$ and the measured fluorescent radiation being received from an irradiated surface portion of the skin only. Kollias et al.'059 fails to disclose the size of the fiber optic cable that receives the measured fluorescent radiation, however, Kollias et al.'059 does disclose that the fiber optic cable that delivers radiation to the skin is at least $0.2cm^2$. It would have been within the skill of the art to use the same sized fiber optic cable to receive the measured fluorescent radiation as the fiber optic cable used to deliver the radiation, since Kollias et al.'059 fails to disclose the size of the return fiber optic cable and Kollias et al.'059 teaches the use of a fiber optic cable (the radiation delivery fiber optic cable) capable of being used as the return fiber optic cable. Anderson et al.'127 teaches that fiber optic bundles comprising separate radiation and delivery fibers are an alternate equivalent to a fiber optic bundle comprising a single fiber wherein the single fiber both delivers and receives diagnostic radiation data to and from the skin of a patient (col. 17, lines 55-67). It would have been within the skill of the art to substitute a fiber optic bundle comprising a single optic fiber to both deliver radiation and receive radiation from the same skin site, as taught by Anderson et al.'127, for the multiple fiber probe of Kollias et al.'059, since it has generally been held within the skill of the art to substitute alternate equivalent expedients.

Response to Arguments

5. Applicant's arguments, see Remarks, filed 03 December 2007, with respect to the rejection(s) of claim(s) 32-40, 43-58 and 60-66 under 102(e) have been fully considered and are persuasive. Therefore,

the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Kollias et al.'059, Anderson et al.'127 and Carim et al.'226, as discussed above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ETSUB D. BERHANU whose telephone number is (571)272-6563. The examiner can normally be reached on Monday - Friday (7:00 - 3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768

EDB